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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,590	09/30/1998	JEFFREY SCHLOM	701433	8846
45733 7590 02/04/2009 LEYDIG, VOIT & MAYER, LTD. TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731				
			EXAMINER	
			CANELLA, KAREN A	
		ART UNIT	PAPER NUMBER	
		1643		
		MAIL DATE	DELIVERY MODE	
		02/04/2009 PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/155,590

**Applicant(s)**

SCHLOM ET AL.

**Examiner**

Karen A. Canella

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-15, 25, 27, 32-34, 66-68 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 27, 32-34, 66-68 and 70-72 is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_

### **DETAILED ACTION**

Claims 11, 12 and 15 have been amended. Claims 11-15, 25, 27, 32-34, 66-68 and 70-72 are pending and under consideration.

Claims 12-15 are objected to because of the following informalities: The claims fail to conform to the Sequence Rules. It is noted that the current CRF has only 14 sequences. Applicant submitted a new electronic format on May 8, 2008. However, this submission was defective because it was in pdf format rather than an ASCII text file.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

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Claims 11-14 are drawn to a genus of mutant ras peptides comprising fragments of the amino acid sequence indicated as Xaa1LeuXaa2ValValGlyAlaXaa3GlyVal wherein the fragments retain the Xaa1 residue, and wherein when Xaa2 is Val, then Xaa1 is Tyr, as well as a genus of mutant ras peptides which consists of fragments of the amino acid sequence indicated as Xaa1LeuXaa2ValValGlyAlaXaa3GlyVal wherein the fragments retain the Xaa1 residue, and wherein Xaa2 is Val, then Xaa1 is Tyr.

Claim 15 is drawn to a peptide consisting of between 8 and 13 amino acids, wherein said peptide is SEQ ID NO:15 or a fragment of SEQ ID NO:15, wherein Xaa1 is Tyr, Xaa2 is any amino acid and Xaa3 is Asp.

The originally filed disclosure describes TyrLeuValValValGlyAlaAspGlyVal (SEQ ID NO:11, page 11, lines 8-9) which meet the criteria of the instant claims 11-14 to the extent that when Xaa2 is Val, then Xaa1 is Tyr. The specification further describes the peptides of SEQ ID NO:1-6 (page 10), SEQ ID NO:12 (page 19), and SEQ ID NO: 13 and 10 (page 20). In all of these peptides Xaa2 is Val; but Xaa1 is Lys rather than Tyr. Thus, the specification fails to adequately describe a genus of truncated peptides Xaa1LeuXaa2ValValGlyAlaXaa3GlyValGlyLysSer wherein the fragments retain the Xaa1 residue, and wherein when Xaa2 is Val, then Xaa1 is Tyr or a genus of peptides from 8 to 13 amino acids wherein the peptide is SEQ ID NO:15 or a fragment of SEQ ID NO:15, wherein Xaa1 is Tyr and Xaa3 is Asp..

One of skill in the art would reasonable conclude that applicant was not in possession of the claimed invention at the time of filing.

Applicant argues that the specification describes the mutant ras peptides comprising 8-13 amino acids on page 10 of the spec, lines 1-4). Applicant argues that the specification teaches mutant ras peptides containing a substituted. at position 12 relative to normal ras, and that mutant ras peptides can contain additional substitutions, such as at position 5 or 7 relative to normal ras (page 11, lines 5-9, page 20, lines 22-24, page 47, lines 10-12, as well as original claims 10-24). This has been considered but not found persuasive. Instant claims 11-15 require that the peptide mutants and fragments comprising residue Xaa1. In order to comply with the written description requirement,

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the originally filed specification must support the specific genus of peptides now claimed. None of the textual citations provided by applicant adequately describe the instant genus of peptides. Applicant argues that the disclosure of SEQ ID NO:2-6 contain a substitution at position 12 relative to normal ras, but although missing the substitutions at position 5 and 7 the specification expressly teachings that variant include the substitution of lysine at position 5 relative to normal ras and/or a substitution of valine at position 7 relative to normal ras (specification, page 11, lines 6-7 and page 47, lines 10-12). this has been considered but not found persuasive. Disclosure in an application that merely renders the later-claimed (by amendment) invention obvious is not sufficient to meet the written description requirement of 35 USC 112, first paragraph. *Lockwood v American Airlines, Inc.*, 41 USPQ.2d 1961 at 1966 (CAFC, 3/4/97).

Claims 25, 27, 32-34 and 66-72 are allowable.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicant's amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643